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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/638,234	08/08/2003	Jacques Van Snick	LUD 5582.1 DIV (10019655)	4108

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EXAMINER	
MERTZ, PREMA MARIA	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/638,234	VAN SNICK ET AL.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-62* is/are pending in the application.

4a) Of the above claim(s) *60-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 44-59), species "bronchial hyperresponsiveness", and species "ovalbumin" on 11/22/2005 is acknowledged. The traversal is on the ground(s) that the restriction is improper since a search for the method of Group I would inevitably involve a search of the composition. However, contrary to Applicants arguments, the inventions are distinct, each from the other because the inventions of Groups II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the inventions are distinct because the composition of invention II may be used in the claimed *in vivo* method, but it can also be used *in vitro* as antigen to bind and purify antibodies in immunochromatography. Therefore, a search for the composition would not necessarily reveal art for a method of using the composition *in vivo*.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter as defined by MPEP. § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP. § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

The Groups as delineated in the restriction requirement 10/26/2005 are patentably distinct one from the other such that each invention could, by itself, in principle, support its own separate patent (as shown by the arguments put forth in the written restriction requirement).

The requirement is still deemed proper and is therefore made FINAL.

Claims 60-62 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

2. Applicants are requested to update the status of the prior applications to which the instant application is claiming benefit. The status of nonprovisional parent 09/490,586 should be updated and the expression, "Patent No. 6,645,486" should follow the filing date of the parent application.

Claim rejections-35 USC § 112, first paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3a. Claim 52 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 52 recites "wherein said subject is in need of reducing production of a Th2 cytokine" which language is new matter in the claim, since the instant specification fails to

disclose such a limitation. The specification fails to provide proper support for this language in the claims for the following reason:

In the specification page 1, lines 13-19 discloses:

"Cytokines are involved in many biological functions and are major mediators of the immune response. They are associated with the initiation and progression of various autoimmune diseases. For example, tumor necrosis factor α (TNFα), interferon γ (IFN γ) and interleukin-l (IL-1) have been associated with diabetes and the destruction of islet cells, the elevated production of Th2 cytokines have been associated with asthma, and interleukin-l2 (1L-l2) has been associated with rheumatoid arthritis."

Furthermore, on page 1, lines 24-27, the specification discloses:

"Since its discovery as a T- and mast cell-growth factor produced by Th2 cells, the physiological processes in which for IL-9 is known to have a role have been gradually expanded."

The specification does not disclose the specific limitation of "wherein said subject is in need of reducing production of a Th2 cytokine" This rejection can only be obviated by reciting the specific limitation for which there is support in the instant specification.

Claim Rejections - 35 USC § 112, first paragraph, non-enablement

3b. Claims 44-59, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for inhibiting IL-9 activity in a subject suffering from bronchial hyper-responsiveness comprising administering a conjugate of IL-9 and a carrier ovalbumin, does not reasonably provide enablement for a method for inhibiting IL-9 activity in a subject in need thereof by administering a conjugate of IL-9 and a carrier to a subject who is in

need of reducing production of "a" Th2 cytokine or a method for inducing an elevated titer of an antibody by administering a conjugate of IL-9 and a carrier to a subject for neutralization of IL-9 in all conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claim 44, for example, is drawn very broadly to methods of treating all conditions caused by IL-9 by administering a conjugate of IL-9 and a carrier to inhibit IL-9 activity. The specification, Example 3, on pages 18-19, only demonstrates the inhibition of IL-9 activity determined by assaying for eosinophilia, while Example 4, on pages 20-21 demonstrates inhibition of IL-9 activity by reduction in expulsion of parasites. The specification fails to provide any guidance for the successful inhibition of all conditions by administering a conjugate of IL-9 and a carrier to inhibit IL-9 activity. For example in The Cytokine Facts Book (1994), Robin Callard and Andy Gearing. Academic Press Inc. San Diego, CA, (page 79, lines 4-8) discloses that IL-9 enhances the proliferation of erythroid precursors. Based solely on Applicants demonstration in the instant specification, it would be clearly impossible for one skilled in the art to inhibit IL-9 activity in a patient with enhanced erythroid proliferation.

Furthermore, claim 52 recites "...wherein said subject is in need of reducing production of a Th2 cytokine". However, the specification is only enabling for a method for reducing "IL-9" activity in a patient suffering from bronchial hyper-responsiveness, by administering to the patient a conjugate of IL-9. Resolution of the various complications in regards to using an antigen to generate an antibody that is immunoreactive for the given protein used as a therapeutic agent is highly unpredictable. One of skill in the art would have been unable to practice the

invention without engaging in undue trial and error experimentation. In order to practice the invention using the specification and the state of the art as outlined below, the quantity of experimentation required to practice the invention as claimed *in vivo* would require the *de novo* determination of pharmaceutical formulations of the antigen to generate an antibody that is immunoreactive for the antigen which is given as a therapeutic agent, and symptoms to correlate with inhibition of the target protein. In the absence of any guidance from the specification, the amount of experimentation would be undue, and one would have been unable to practice the invention over the scope claimed.

The specification as filed does not provide any guidance or examples that would enable a skilled artisan to use the disclosed methods for inhibiting IL-9 in all conditions using a conjugate of IL-9 and a carrier to generate an antibody that is immunoreactive and as a therapeutic agent in a patient. Additionally, a person skilled in the art would recognize that predicting the efficacy of using a given antigen to treat all conditions involving IL-9 by generating an antibody that is immunoreactive for the antigen as a therapeutic agent *in vivo* based solely on *prophetic suggestion* as highly problematic (see MPEP §2164.02). Thus, although the specification prophetically considers methodologies of using the IL-9 conjugate as a therapeutic agent, such a disclosure would not be considered enabling since the state of protein aggregation is highly unpredictable. The factors listed below have been considered in the analysis of enablement [see MPEP §2164.01(a) and *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)]:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;

(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Claim rejections-35 U.S.C. 112, second paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 44-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 44, lines 1-2, is rejected as vague and indefinite because it recites "subject in need thereof". The metes and bounds of the claim are unclear because it is unclear what conditions the patient is suffering from.

Claim 52, is vague and indefinite because it recites "reducing production of a Th2 cytokine". It is unclear what the metes and bounds of the claim are and which Th2 cytokines are encompassed by the claims.

Claim 53, lines 4-5, is vague and indefinite because it recites "which neutralize it". It is suggested that the claim be amended to recite "which neutralizes IL-9".

Claims 45-51, 54-59 are rejected as vague and indefinite insofar as they depend on the above rejected claims for their limitations.

Claim rejections-Double Patenting

Non-statutory double patenting rejection (obviousness-type)

5. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and 8 may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5a. Claims 44-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,645,486 (‘486). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 1 of U.S. Patent No. ‘486 (having all three common inventors with the instant application), claims a method for reducing activity of IL-9 in a subject suffering from asthma, mast cell activation, eosinophilia and allograft rejection by administering a conjugate of IL-9 and

a carrier. In instant claims 44-59, administration of a conjugate of IL-9 and a carrier to treat all conditions associated with increased IL-9 activity are claimed. Instant claims 44-59 are generic to claims 1-11 in the patent and encompasses subject matter to which the allowed claims are a species because a method of treating all conditions involving increased IL-9 activity include a method of treating pathological conditions asthma, mast cell activation, eosinophilia and allograft rejection involving increased IL-9 activity. However, the patent claims are obvious from the instant claims because the patent claims are directed to specific embodiments encompassed by instant claims 44-59. The patented product is included in instant claims 44-59. It would have been obvious to one of ordinary skill in the art at the time the present invention was made, that a method of administration of a conjugate of IL-9 and a carrier to treat all conditions associated with increased IL-9 activity included a method for reducing activity of IL-9 in a subject suffering from asthma, mast cell activation, eosinophilia and allograft rejection by administering a conjugate of IL-9 and a carrier. The patented claims if infringed upon would also result in infringement of the broad claims of the instant application. Allowance of the pending claim, therefore, would have the effect of extending the enforceable life of the allowed claims beyond the statutory limit.

Conclusion

No claim is allowed.

Claims 44-59 are rejected.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

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Art Unit 1646
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